

### REMARKS

Claims 49-51, and 117-144 are pending in the application. Claim 49 has been revised to further clarify the claim by reciting an abrading surface creating a predetermined surface contour in an end plate of one of the adjacent vertebral bodies. This feature was inherent in original claim 49,<sup>1</sup> but has been added merely to clarify that the surface contour created by the abrading surface is in the end plate of the vertebral body. The amendment to claim 49 is fully supported by the specification and original claims, *inter alia*, at original claim 25, and paragraph [0020]. No new matter is presented by the amendments. The amendment requires no further consideration or search since it was inherent in claim 49. Accordingly, applicants respectfully request entry thereof, and reconsideration of claims 49-51, and 117-144 in light of the following remarks.

Applicants are submitting herewith a Declaration of Carlos Gil. Mr. Gil's declaration is being submitted to address the newly cited art in the Office Action, and consequently, could not have been submitted earlier. Accordingly, applicants respectfully request that the Examiner consider and make of record the attached declaration.

Turning now to the merits of the Action, claims 49, 51, 121, 122, and 125-128 are newly rejected under 35 U.S.C. §102(b) as being anticipated by Frigg, *et al.*, U.S. Patent No. 5,041,119 ("Frigg"). Applicants respectfully traverse this rejection.

Frigg fails to disclose all of the elements recited in the present claims, and in fact, it is impossible for the Frigg device to include all of the elements recited in the claims, one of which requires the device to create a space between adjacent vertebral bodies to receive an insert. For example, Frigg fails to disclose "an apparatus for preparing a space in the human spine to receive an insert between adjacent vertebral bodies," and "an abrading element having at least one abrading surface selected to create a predetermined surface contour in an end plate of one of the adjacent vertebral bodies in the narrow space between two opposing vertebral bodies." Each of these elements is recited in independent claim 49, the only independent claim included in this

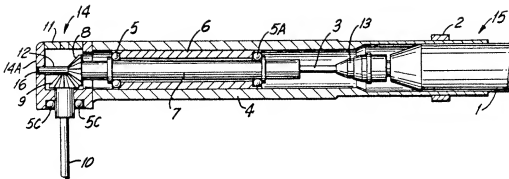
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<sup>1</sup> The Examiner will appreciate that the end plates of vertebral bodies are the portions of the vertebral bone positioned adjacent the disc space.

rejection. The Action acknowledges that these elements are positively recited elements of the claims to be given due consideration and weight in assessing the scope of the claims, by first alleging that Frigg “disclose an apparatus for preparing a space in the human spine to receive an insert between adjacent vertebral bodies” (Action, at page 2), and then further alleging that Frigg discloses an “abrading element having at least one abrading surface selected to create a predetermined surface contour in one of the adjacent vertebral bodies. . .” (Action, at page 2). Applicants respectfully submit that Frigg fails to disclose these features recited in independent claim 49.

Applicants have attached hereto a declaration by Carlos Gil, a design engineer in the medical orthopedic industry for over 20 years. Mr. Gil is an employee of Medtronic Sofamor Danek. The current assignee is a wholly-owned subsidiary of Medtronic Sofamor Danek. Mr. Gil testifies that the type of drilling apparatus described and claimed in the present application is the type of device that he has worked with and developed for most of his professional career (Gil declaration, at ¶3). Mr. Gil is well qualified to opine as to how a person of ordinary skill in the art would read and understand the Frigg patent (*Id.*, at ¶5).

Mr. Gil states in the attached declaration that the presently claimed device has a profile that allows the abrading element to fit in the narrow space between two opposing vertebral bodies in the cervical spine of a patient, and at the same time form a contour in one of the adjacent vertebral bodies (*Id.*, at ¶6). After reviewing the present application and the disclosure of the Frigg patent, including their respective drawings, Mr. Gil notes that the various embodiments disclosed in the Frigg patent include conventional or hollow drill bits inserted over a guide wire that can be used, for example, on the spinal column or pelvis, where bone screws must be set with extreme precision (*Id.*, at ¶9). In particular, Mr. Gil notes in reviewing the figure of the Frigg patent that the drill bits are elongated and are used to form a hole in a bone for insertion of a bone screw (*Id.*, at ¶s 9 and 10) — figure 1 of Frigg being reproduced below:



Mr. Gil testifies that the device disclosed in Frigg fails to include at least the following elements recited in the present independent claims (*Id.*, at ¶11):

- a) an apparatus “for preparing a space in the human spine to receive an insert between adjacent vertebral bodies.” (*See* Claim 49);
- b) “an abrading element having at least one abrading surface selected to create a predetermined surface contour in an end plate of one of the adjacent vertebral bodies in the narrow space between two opposing vertebral bodies.” (*See* Claim 49); and
- c) “an abrading element having at least one convex abrading surface selected to create a concaval-convex contour in one of the adjacent vertebral bodies.” (*See* Claim 130).

As noted earlier, the Action recognizes that the claims require an apparatus that can prepare a space between adjacent vertebral bodies in the human spine to receive an insert. Mr. Gil testifies that it is *impossible* to use the device of Frigg to drill in-between adjacent vertebral bodies — a requirement of the claims (*Id.*, at ¶12). The reason for this is set out in paragraphs 13-15 of the attached declaration.

Applicants have provided sufficient evidence to refute the allegations in the Action that Frigg discloses: (a) an apparatus for preparing a space in the human spine to receive an insert between adjacent vertebral bodies; and (b) an abrading element having at least one abrading surface selected to create a predetermined surface contour in an end plate of one of the adjacent vertebral bodies. Frigg therefore cannot anticipate the present claims because it fails to disclose at least two elements recited in independent claim 49. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

The Action on page 4 rejects claims 123 and 124 under 35 U.S.C. §103(a) as being unpatentable over Frigg. The Action alleges that it would have been obvious to “have constructed the angle between the abrading element shaft and the shaft [to be] approximately 96°, and the maximum height of the abrading element [to be] nine millimeters, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering optimum or workable ranges involves only routine skill in the art,” citing *In re Aller*, 105 USPQ 233. Applicants respectfully traverse this rejection.

Frigg fails to disclose all of the elements recited in independent claim 49, from which dependent claims 123 and 124 depend. Accordingly, Frigg cannot render obvious these claims. Applicants further respectfully submit that the Action has taken a far more expansive reading of the limited holding in *In re Aller* than permissible. Indeed, the holding of *In re Aller* was severely limited and restricted in *In re Antonie*, 559 F.2d 618 (CCPA 1977), which held that only known (or “art recognized”) result-effective variables would have been obvious to optimize (*see*, MPEP 2144.05). In the present case, Frigg fails to disclose that the angle between the abrading element shaft and the shaft is a result-effective variable, and likewise fails to disclose that the maximum height of the abrading element is a result-effective variable.

In fact, Frigg suggests that these elements are not result-effective variables by describing the use of X-radiation to view the device as it is drilling, thereby enabling direct viewing and negating any height or angle requirement to make an appropriately-sized drill hole. The width of the drill bit might arguably be considered result-effective since this will determine the size of the bone screw to be inserted, but the height of the drill bit is not relevant. The sole figure of Frigg supports applicants’ argument insofar as the length of the drill bit 10 is truncated, thereby indicating that any length would suffice. The Action has failed to come forward with any additional evidence that would suggest that the angle between the abrading element shaft and the shaft or the maximum height of the abrading element are art-recognized result-effective variables in Frigg’s device. Accordingly, as set out in *In re Antonie*, which modified and limited the *In re Aller* holding, a skilled artisan would not have found it obvious to vary the angle or the maximum height, as alleged in the Action. Claims 123 and 124 would not have been obvious for these reasons, and applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Page 5 of the Action rejects claim 129 under 35 U.S.C. §103(a) as being unpatentable over Frigg, in view of Fattaleh, U.S. Patent No. 3,921,298 ("Fattaleh"). Applicants respectfully traverse this rejection.

Frigg fails to disclose all of the elements of independent claim 49, from which claim 129 depends. The Action also has failed to come forward with evidence that Frigg discloses an abrading element having a groove about its perimeter, as required in dependent claim 128, from which independent claim 129 depends. Fattaleh is only relied upon for its alleged disclosure of a drive mechanism that comprises a belt (*see*, Action, at page 5), allegedly cooperating with a groove on an abrading element. But Fattaleh also discloses a beveled gearing surface 21 that is attached to a longitudinal rod 19 comprising the drive mechanism. This gearing surface then cooperates with toothed wheel 28, which includes a groove to accept the belt shown in Figure 3. The opposite end of the abrading element of Frigg has a beveled gearing that cooperates with the beveled gear from the drive mechanism, and does not include a groove (in Fattaleh, this would be gear 21).

The Action has not advanced any sound, scientific rationale as to why a skilled artisan would combine Frigg and Fattaleh in the manner alleged. Applicants respectfully submit that the combination would require a complete re-design of the drill bit 10 of Frigg (so it no longer would contain a beveled gear, but for some reason would be re-designed to contain a groove), and the combination would require the addition of the toothed wheel 28 and belt, which would significantly complicate the design of the Frigg device, and add to its weight and length. A skilled artisan therefore would not have combined Frigg and Fattaleh in the manner asserted in the Action. Even if combined, the combined disclosures still fail to render obvious the present claims because Frigg fails to disclose all of the elements of independent claim 49. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

Pages 5-7 of the Action reject claims 50, 117-120, and 130-143 under 35 U.S.C. §103(a) as being unpatentable over Frigg in view of Pomp, U.S. Patent No. 5,312,207 ("Pomp"). The Action recognizes that Frigg fails to disclose a number of features recited in the present claims that relate to the specific shape and contour of the abrading element. The Action relies on Pomp as providing the missing disclosure. Applicants respectfully submit that Frigg and Pomp would

not have been combined, but even if combined, the combined teachings fail to include all of the elements recited in the present claims.

Frigg fails to disclose all of the elements recited in independent claim 49, from which claims 50, and 117-120 depend, and Frigg fails to disclose all of the elements recited in independent claim 130, from which claims 131-143 depend. The drill bit of Pomp is *NOT* designed to create a surface contour in a bone, but rather is designed to provide a cylindrical drill bit (much like a Forstner bit) capable of cutting a cylindrical hole in wood or metal, due to its superior chip removal properties. Accordingly, the drill bit of Pomp can be used to cut deeper holes in a wood or metal workpiece, a feature not required, and in fact, undesirable in drill bits used to create very precise and limited-depth holes in vertebral bodies to accept bone screws.<sup>2</sup> The combined disclosures therefore fail to disclose all of the features recited in the present claims, and for this reason, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

A person skilled in the art would not have combined Frigg with Pomp. The Action fails to provide any sound rationale as to why a skilled artisan would have combined Frigg with Pomp, other than the unsupported allegation that a skilled artisan would have “substituted the abrading element of Frigg et al. with the abrading element of Pomp in order to achieve the predictable result of cutting holes with the abrading element” (Action at pages 6 and 7). But Frigg already cuts holes, so what does Pomp add to Frigg that is not already present in Frigg? The only advantage of Pomp’s design is to create larger cylindrical holes without having to remove the drill bit — again a feature that actually is a disadvantage in a bone drilling apparatus like that disclosed in Frigg, which is used to create a limited-depth hole to receive a bone screw. A skilled artisan therefore would have no reason to combine Pomp with Frigg, and would actually have many reasons not to combine the respective disclosures, not the least of which would be patient safety. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

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<sup>2</sup> Most drill bits used to create holes in vertebral bodies to accept bone screws are provided with stops or other mechanisms to prevent excessive drilling, which can cause paralysis or death. Having a drill bit with increased depth of drilling capabilities would not be desirable at all in a drill used to create a space in a vertebral body to accept a bone screw.

Page 7 of the Action rejects claim 144 under 35 U.S.C. §103(a) as being unpatentable over Frigg in view of Pomp, and further in view of Fattaleh. Applicants respectfully traverse this rejection.

The combination of Frigg and Pomp fails to satisfy all of the elements of independent claim 130, from which claim 144 depends. The Action has failed to come forward with evidence that Frigg or Pomp discloses an abrading element having a groove about its perimeter, as required in dependent claim 143, from which claim 144 depends.<sup>3</sup> Fattaleh is only relied upon for its alleged disclosure of a drive mechanism that comprises a belt (*see*, Action, at page 7), allegedly cooperating with a groove on an abrading element. But Fattaleh also discloses a beveled gearing surface 21 that is attached to a longitudinal rod 19 comprising the drive mechanism. This gearing surface then cooperates with toothed wheel 28, which includes a groove to accept the belt shown in Figure 3. The opposite end of the abrading element of Frigg has a beveled gearing that cooperates with the beveled gear from the drive mechanism, and does not include a groove (in Fattaleh, this would be gear 21).

There is no sound, scientific rationale as to why a skilled artisan would combine Frigg and Fattaleh in the manner alleged in the Action, and the Action has provided none. Applicants respectfully submit that the combination would require a complete re-design of the drill bit 10 of Frigg, or the combined drill bits of Frigg and Pomp (so it no longer would contain a beveled gear, but for some reason would be re-designed to contain a groove), and the combination would require the addition of the toothed wheel 28 and belt, which would significantly complicate the design of the device, and add to its weight and length. A skilled artisan therefore would not have combined Frigg, Pomp, and Fattaleh in the manner asserted in the Action. Even if combined, the combined disclosures still fail to render obvious the present claims because Frigg and Pomp fail to disclose all of the elements of independent claim 130. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

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<sup>3</sup> The Action alleges on page 6 that the abrading element of Pomp comprises a groove about its perimeter, citing to Figure 6, next to ref. number 16. There might be a somewhat inclined surface in Figure 6, but there is no groove.

In view of the foregoing, applicants respectfully submit that the present claims are in condition for allowance. An early notice to this effect is earnestly solicited. Should there be any questions concerning the foregoing, or should the Examiner believe that a telephonic interview would serve to further advance prosecution of the claims, the Examiner is courteously invited to contact the undersigned at the telephone number listed below.

No additional fee is believed to be required for entry and consideration of this response. Nevertheless, in the event that the U.S. Patent and Trademark Office requires any additional fee to enter this response or to maintain the instant application pending, please charge such fee to the undersigned's Deposit Account No. 07-1700.

Respectfully submitted,

Dated: Feb. 4, 2008

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